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DEVELOPMENT AND APPLICATION OF A TENDON PROSTHESIS FOR EARLY FU--ETC(U)

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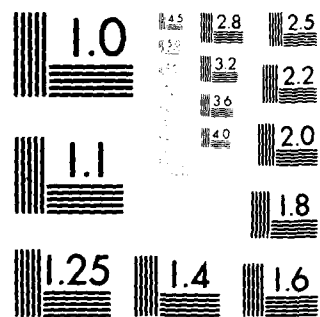
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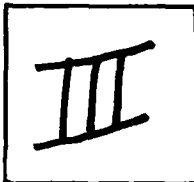


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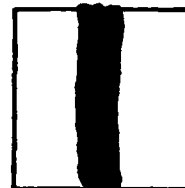
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DEVELOPMENT AND APPLICATION OF A TENDON PROSTHESIS  
FOR EARLY FUNCTIONAL RESTORATION OF THE HAND

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**DEVELOPMENT AND APPLICATION OF A TENDON PROSTHESIS  
FOR EARLY FUNCTIONAL RESTORATION OF THE HAND**

**ANNUAL REPORT**

by

**James M. Hunter, M.D.**

**September 1975**

**(For the period 1 July 1972 to 30 June 1973)**

**Supported by**

**U.S. ARMY MEDICAL RESEARCH AND DEVELOPMENT COMMAND  
Fort Detrick, Frederick, Maryland 21701**

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**Jefferson Medical College  
Thomas Jefferson University  
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20. ABSTRACT (Continue on reverse side if necessary and identify by block number)  Experiments were carried out to determine the feasibility of using stainless steel woven fiber tape for distal attachment to bone. The steel tapes were placed in 5 mm osteoperiosteal bone flaps. Forty-eight samples remained in for 4, 8 and 12 weeks. They were studied by tensile testing and histologic examination. Tape shearing was irregular leaving fibers imbedded in bone. It was concluded that 316 L material approached 50% initial strengths. It would be necessary to make tape fiber textile rearrangements to improve		

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porosity and again the study showed that 304 stainless steel was not acceptable. Porous metal ingrowth study should be continued. The proximal end attachment study was continued in the soft tissues of dog muscle and tendons. New materials were studied using DuPont Fiber B and paralytic graphite fiber. Various types of tape configurations are being studied to permit silicone surface attachment and porosity for tissue ingrowth.

Quantitative and semi-quantitative immunochemical analysis of canine synovial fluid was started. Preliminary results were analyzed utilizing canine and joint tendon fluid. A study of the microblood supply to tendons was begun in still-born human materials developed through the Anatomy Laboratory. Specimens were prepared in the Department of Anatomy and a special injection latex india ink technique is currently under study. To enhance early tissue healing of the distal juncture of the tendon implant, preliminary studies using weak electrical fields was conducted in rabbits. Fields of 15 to 30 microamps were applied to skin incisions and it was concluded that D. C. current in the range of 15 to 30 microamps appeared to be beneficial in enhancing the rate of wound healing. The preliminary results of metal tape ingrowth in the dog indicated a fall-off in strength between 12 and 16 weeks. This may be extremely significant as far as this type of study is concerned. It would suggest that delayed tissue re-action may offset strength.

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The Restoration of Early Hand Function, Following Traumatic Injury  
by the Use of an Active Gliding Tendon Prosthesis

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Title: Development and Application of a Tendon Prosthesis for Early Functional Restoration of the Injured Hand

1. Type of Project: Definitive Study
2. Technical Objective: The technical objective of this proposed research study is to extend the development and application of the "Hunter Tendon" so that this implant may be used as an early and permanent active tendon prosthesis following injury to the flexor tendon system in the hand.
3. Hypothesis: The working hypothesis german to this program is that an acceptable permanent prosthesis can be developed using the fundamental approach afforded by the "Hunter Tendon", a gliding artificial tendon.

In order that this technique becomes capable of earlier application following injury and long-term tendon replacement, it is recognized that design changes may be required in these areas relating to materials of construction and methods of attachment of bone, tendon and muscle. In addition, the basic knowledge of tissue growth, response and acceptance to a tendon prosthesis should be augmented by further laboratory study.

4. Background

Basis and Previous Work: During the past year, the investigation continued in the study of three distinct areas, each contributing to the overall goal of the development of a permanent flexor tendon prosthesis.

The major activity during 1972-1973 was the investigation to define the optimum method for distal end attachment. The other two areas concerned the refinement of the tendon prosthesis design and the basic healing process of the tendon.

A. Distal and Proximal End Attachments

1. Distal Attachment

Evaluation of the first year's results combined with published experimental data revealed that the most desirable mode of load-bearing attachment between a prosthesis and the natural tissue permitted the infiltration of fibroblastic fibrils into the interstices of the prosthesis. In time, this ingrowth developed into a collagenous mass well accepted organically, and capable of accepting and transferring load-bearing stresses in the manner of the natural tissue. Consequently long-term implants have been conducted during the past year, as noted in our semi-annual report of December 28, 1972. These studies conducted in dogs investigated the implantation of 5 mm. wide by 1 mm. thick tapes of stainless steel wire fibers in two patterns. The type 304 S.S. was woven into pattern No. 1702 and had a pore size of about 100 microns. The type 316L S.S. was patterned in No. 1702 B, yielding a pore size of approximately 250 microns.

The purpose of these experiments was to determine the feasibility of using a tendon prosthesis composed of stainless steel fibers woven into a tape, the shaft of which could be coated with silicone rubber, leaving both ends bare so as to present to the natural tissue and cells a matrix within which the cellular ingrowth could commence. The protocol for the surgical implantation was described in the semi-annual report of December 28, 1972. It suffices to say that the tapes, having the medial and lateral metacarpals of the dog so that a surface area of 0.45 cm<sup>2</sup> was in contact with the bone. This was done by means of an osteoperiosteal flap made, using an osteotome and reaming out the medullary canal and then placing 5 mm. of the tape within the flap area. A total of 48 experimental samples were permitted to remain in situ for time intervals of 4, 8, 12 and 16 weeks, following which they were surgically removed for strength determinations by tensile testing and histological examination. Fig. 1 is an x-ray photograph of the medial and lateral aspects of a 12 week sample immediately at the removal from the dog.

The tensile testing conducted on a Thwing-Albert Testor at a crosshead speed of 12.5 cm. per min., has been completed and the data are being evaluated. The preliminary results are shown on Fig. 2. Fig. 3 is an x-ray photograph of a 12 week specimen following tensile testing. Note the fibers remaining in the cavity formed in the bone. Fig. 4 is a photograph at low magnification, showing these same fibers and showing the same bone.

Initial evaluations indicate that the scatter of values at each of the implant periods, as can be seen on Fig. 2, is the result of tape failures. The tapes are shearing, unravelling or pulling out of the cortex, leaving behind a large amount of imbedded fibrils. A further preliminary conclusion is that the weaving techniques are not satisfactory. This is derived as a result of the malfunctioning of the tapes during the pull tests in addition to the observation that the tape ends begin unravelling immediately after they are cut to size prior to implantation. Still an additional conclusion is that the materials, types 304



and 316L stainless steel, are not suited to this application in this form of small diameter fibers. Although it is known that 304 S.S. will react in the physiological saline environment, type 316L S.S. is recommended as being non-reactive. However, these data demonstrate a marked decrease in strength after 12 weeks implantation. A tentative reason for the decrease in strength may be because of the greatly increased surface area presented by the metal fibers which is available for reaction within the hostile environment of the interstitial fluids.

On the positive side, it is interesting to note that the strength of union between the metacarpal and the tape, in the case of the 316L material, approaches 50 per cent of the initial strength of the 5 mm. tape, as received from the knitting mill (12 kg. compared with 26.3 kg.). Further, the initial increase of strength during the first 4 weeks presages important clinical information as regards the treatment of the injured hand immediately post-operative. Moreover, the concept of tissue infiltration and penetration into a woven or otherwise porous metal end attachment appears sound and will be the continued subject of investigation.

## 2. Proximal Attachments

Preliminary studies have been started in attempting to obtain a reasonable time-strength bond between the prosthetic end attachment and soft tissue. Implants of polyester velour and stainless steel No. 160 gauge mesh screens have been made in the vastus laterali of the dog. At timed intervals, the implant area will be excised and prepared for histological and microscopic examination. Additional implants will be made to investigate the strength relationships as a function of time in situ.

The technique announced by the Soviets in which the implantation of minced muscle fragments into the original muscle bed resulting, in a few months, in a new, full muscle is being reviewed with the ultimate goal of its possible application to our study for finding a feasible solution to the proximal end attachment to soft tissue.

## B. Configurational Changes - Material Selection

As noted above, the long-term implant study has indicated the need for a possible change in the design configuration of the tendon prosthesis. Preliminary evaluation has indicated that two new synthetic materials, Dupont Fiber B and B.R.D. 49 have superior qualities as regards strength, density, expansion and ease of manufacture. Sample quantities of these materials have been ordered and are presently being woven into 5 mm. wide ribbons. Upon receipt, they will be evaluated by static tensile testing and, if satisfactory, implant tests will be conducted.

In addition, a review of the weaving technique has indicated that braiding may also be used to meet our requirements of high strength, low expansion and controlled porosity. The Philadelphia College of Textiles and Science is presently braiding samples of a pyrolytic graphite fiber to our specifications so that we may conduct studies both on this material and method of construction. End attachments for these non-metallic ribbons can take the form of metal screens and cylindrical plugs, polyester velour and meshes.

### C. Elucidation of the Healing Process

1. The immunochemical technique developed to characterize the teno-synovial fluid has been temporarily delayed because of the difficulties in maintaining an immobilization period following surgical implantation of a Hunter Sliding Tendon in the hand of a chimpanzee. The selection of the chimpanzee as the experimental model rather than the dog was predicated on the fact that the tendon excursion in the chimp is about 7 to 9 cm. whereas in the dog it averages 0.7 cm.. (In the human, the procedure will be conducted on a stump-tailed monkey that is considerably more docile and is presently undergoing arm immobilization conditioning.

2. Qualitative and semi-qualitative immunochemical analysis of canine tenosynovial fluid has begun. This study is being done on the basis of the comparison of constituents of the serum, normal synovial fluid, taken from the knee joint and the fluids bathing the tendon. The preliminary results are summarized in the following table:

ANTIBODY TITERS

Constituent	Serum	Synovial	Tendon
Pre-Albumin	0-1 +	2 +	1 +
Albumin	3 +	2 +	2 +
Immunoglobulin	2 +	1 +	3 +
A/g	3/2	2/1	2/3
I <sub>g</sub> A	3 +	1 +	0-1 +
I <sub>g</sub> A	2 +	0	2 +

The values shown tend to indicate that there is an albumin : globulin ratio reversal in the tendon fluid when compared with serum and normal synovial fluid. In addition, there is very little detectable  $I_{G}$  present in tenosynovial fluid while  $I_{G}A$  is found in a moderate amount. These preliminary results and the values will be further elucidated as more data are gathered. This study will be extended to the analysis of human tenosynovial fluid specimens.

3. It is believed by many that the behavior of the tendon as a tissue is related to its blood supply. Recent studies using radioactive tracer techniques have confirmed the concept of a regimented vascularization of tendons. Nevertheless, an area of controversy still exists as to the microanatomy of the flexor tendon vascularization system. To aid in its elucidation, a program has begun in which stillborns (neonates) gestated age 5-9 months have their axillary arteries cannulated and injected with a material that is a latex solution diluted 1:4 with water and India ink. The solution is further diluted 1:2 for injection into arterioles and 1:8 for capillaries. The material is then processed, dehydrated, sectioned and/or dissected, cleared with either methyl salicylate or a mixture of tricresyl and tributyl phosphate. The resulting specimens are then examined with a dissecting microscope and photographed. A total of 12 neonate extremities have been examined to this time. The preliminary observations are at variance with the published descriptions in two areas, palmar and within the flexor sheath. A full report is presently being prepared. Figs. 5 and 6 show injected cleared specimens of the flexor sheath areas of smooth fetal index fingers demonstrating the dorsally bared vasculature system augmented by the long and short vascular vessels. Magnification is 3 X.

4. The preliminary feasibility study to examine the effect of a weak electric field on wound healing has been concluded. Two series of experiments were conducted, using the rabbit as the experimental animal. In one series, an electric field strength of 15 to 30 microamps was applied to a number of full thickness skin incisions for a total time of 7 days. The other series was a duplicate of the first with the exception that the impressed d.c. electricity was at a level of 1.0 microamps. (Both series used a stimulator designed around a 1.35 v. battery - RM 625 - having a suitable resistance in the circuit to obtain the desired value of current.) The experimental incisions were made on one side of the animal and control incisions were made on the other side of the same animal. The results indicate that a difference in the strength of the wound as determined by tensile testing was obtained in those incisions treated with the 15-30 microamp currents. The ratio of experimental incision strength to control incision varied from 1.00 to 2.25 with the average experiment being 1.56 times stronger than the control. The series of experiments in which a current of 1.0 microamps was applied demonstrated no difference in the tensile strength between the experimentals and control incisions. The conclusions reached from this preliminary feasibility study are that d.c. current in the range of 15-30 microamps appears to be beneficial in enhancing the rate of wound healing as determined by the strength of the wound. Secondly, values of applied amperage of 1.0 microamps or less have no measureable effect on the strength of the healing wound.

## 5. Methods:

The results of the past year's work has permitted a reasonably clear picture to emerge as regards the design of the tendon prosthesis so as to permit a one-step operative procedure for the early restoration of the injured hand.

As noted earlier, the ingrowth studies, using woven stainless steel tapes, have indicated the feasibility of obtaining a reasonable bond between the porous end attachment and the bone in 4 to 8 weeks. Thus, the direction is clear as to the solution of the distal end attachment.

Preliminary studies to effect a solution to the proximal end attachment have also given direction to the investigation. The use of textile woven polyester appears to be a good choice for supporting tissue ingrowth while maintaining initial strength by virtue of the sutures holding the attachment to the soft tissue.

The design problems of the tendon prosthesis shaft have been reduced to the selection of a material having the correct combination of properties, i.e., about 2% elongation, tensile test strength of about 35 kg. (77 lbs.), porosity equivalent to the weave of No. 1702B having a void volume of about 25% (pore size approximately 250 microns).

Thus, the goals of the 1972-73 program, as shown in the report dated May 19, 1972, have been realized. The next series of investigations to bring to fruition these data and design specifications will be the goal of the next year's study. Continuing the delineation of the major areas requiring resolution, work will be continued as follows:

- a) Distal and Proximal Attachment
- b) Tendon Prosthesis Design Refinement
- c) Basic Studies (Elucidation of the Tendon Healing Process)

### A. Distal and Proximal Attachments

Because of the different problems presented by these attachment studies and also because of the difference in the state-of-the-art for each, these will be discussed separately.

#### 1. Distal Attachments

The solution to the long term distal attachment of the prosthetic flexor tendon lies in the acceptance of the non-organic system by the natural organism. This acceptance may be realized by the encapsulation of the device by fibroblastic and/or osteoblastic activity. The experiments conducted to date and shown as preliminary results, demonstrate that the technique of using a stainless steel ribbon or tape made by weaving a multitude of micron-diameter fibers is a valid solution. The values of tensile strength achieved within a relatively short period indicate that the injured hand can be used to a limited extent after about 4 to 8 weeks. The relationship between porosity and tissue ingrowth as measured by pull test strength also is graphically demonstrated in Fig. 2. Although the precise pore size has yet not been determined, a value of 250 microns appears more desirable than 100 microns.

A deferring factor has been uncovered, however, with the use of woven ribbons. This is due to the tendency of the ribbon end to unravel after it has been cut to size prior to implantation. In fact, low magnification studies of the bone/tape used in the implant studies following pull testing reveals that a fair amount of metal fibers remain in the bone where the original cortex flap was raised for the emplacement of the metallic ribbon.

Thus, it is desired to review the metal weavetechnique with the ultimate goal of finding a method whereby the ends of the tape are more tightly woven so as not to have a propensity to unravel, or else to substitute stainless steel screens or meshes for the metal tapes. The screens are manufactured in such a manner as to retain their strength even after cutting to size and shaping by surgical scissors. The porosity can be duplicated between tape and screen through the technique of folding (or lapping) the screen until the void area equals approximately 25 per cent.

The physical attachment of the screen to the prosthesis shaft can be effected by cement, suture, staple, welding, etc.. These methods will be investigated.

The short-term or interim solution to the problem of repair may lie in the direction of using an integral loop at the distal end for attachment by suture, rivet, button or screw to the distal phalanx. Present thinking dictates a tear-drop shaped loop made during the weaving operation of the shaft of the prosthesis. Thus, a strong, continuous bond is formed. The inner side of the loop is lined with a teflon or equivalent spacer properly shaped so that the load placed on the tendon prosthesis is uniformly distributed around the loop, thus keeping the unit stress loading on the looped end at a reasonable design value. Looped prostheses have been ordered for test.

In summation, the next year's work on the distal end attachment will examine two approaches:

- a) Screens suitably designed to maintain the desired porosity and strength
- b) Woven loops suitably lined for uniform load distribution.

The experimental protocol will continue to use dogs as the experimental animal to demonstrate compliance of the test device with the desired goal. Test pieces of stainless steel screens have been received as ordered and range in mesh sizes from 20 to 160. These will be cut into strips 5 mm. wide and 25 mm. long and implanted in the metacarpals of the dog. The surgical techniques will be as previously described in the report of December 28, 1972. These will be surgically removed after 4, 8, 12 and 16 weeks for histological and strength studies.

Looped tendon ends will be obtained as per our specifications and will replace the flexor tendon system in the stump-tailed monkey. This passive sliding tendon will be used for a dual purpose: 1) to examine the efficacy of using a loop as a distal attachment, and; 2) to study the development of the pseudosheath by analysis of the synovial fluids.

## 2. Proximal Attachments

The looped end also is a reasonable approach to the attachment of the tendon prosthesis to a natural tendon stump. Under these circumstances, (where a section of the tendon remains proximally) it is desirable to loop the tendon through the looped end of the prosthesis shaft and then suture it to itself. By this means, an active implant may be achieved.

For the more seriously injured system where the tendon must be completely removed, the problem of proximal attachment becomes a provoking one. The approach to its solution indicates the need for the interaction of regenerating tissue and a firm, porous material that will permit the ingrowth of fibrils of regenerating tissue. To this end, studies will be conducted using suitably shaped (dove-tail, rectangular, fan-shaped) pieces of polyester, velour, fine gauge stainless steel mesh and Dupont fiber BRD 49. Implants will be made in the muscle system of dogs and removed after 4, 8, 12 and 16 weeks to determine acceptance and tensile strength. An histological evaluation will also be conducted after slide mounting of the test samples.

A second and concurrent study will examine the techniques of minced muscle regeneration as described by Studitsky (cited by Carlson in Muscle Biology, R.G. Cassens, Editor, Marcel Dekker, N.Y., 1972). Briefly, this method consists of entirely removing a muscle, mincing it into 1 mm. cubed fragments and implanting the fragments into the original muscle bed. As applied to our problem, it may prove efficacious to remove a portion of the flexor carpi ulnaris or radialis, mince it and then place it in its original bed on top of or intermixed around the shaped proximal attachment. It may be speculated that this approach may enhance the tissue growth through the attachment and also add to the overall strength in tension of the interface.

### B. Tendon Prosthesis Design Refinement

Material selection for the tendon shaft has been narrowed to a small number of candidates as a result of the studies conducted in the previous year. The use of the S.S. 316L has produced problems in weaving. Uniformity is not consistent, thus the porosity may vary from batch to batch. In addition, a potential problem has arisen that requires experimental resolution. The implant studies conducted during this year indicates that there is a fall-off of strength between the 12th week and the 16th week. This is shown on Fig. 2 and occurs on both the S.S. types 304 and 316L. Speculating on the reason for this strength decay, it may be as the result of the chemical attack on the fibers comprising the woven tapes which are exposed to the interstitial fluids. Ordinarily, type 316L S.S. is not reactive in this environment. However, when it is drawn into micron-diameter wire fibers, the surface area is dramatically increased which may permit chemical reaction. To resolve this problem, samples of woven ribbons of type 316L S.S. will be immersed in physiologic saline solution for 4, 8, 12 and 16

weeks and then pull tested. The breaking strength of the immersed samples will be compared with control strips of ribbon as received from the manufacturer.

Dupont Fibers B and BRD 49, in addition to polyester fibers and pyrolytic graphite, are presently the materials of choice. In particular, fiber BRD 49 appears to hold maximum promise. 5 mm. wide ribbons are being woven from these materials and, when received they will be subjected to implant studies after, as received, pull testing is conducted. Both BRD 49 and fiber B are also to be woven with integral looped ends for studies described in the preceding paragraphs.

Both the chimpanzees and the stump-tailed monkeys will be used to investigate the shaft design of the tendon prosthesis.

### C. Basic Studies

1. Pseudosynovial fluid characterization will be continued. All experimental studies in which tendon prostheses are implanted will serve as potential sources of fluid extraction and manipulation. A review of the technique is scheduled early during this period of investigation in order that the relative merit of the technique and its value to the overall program is established. The prognosis at this writing is that the approach is sound and continued work will result in a meaningful contribution to the biochemical characterization of the synovial fluids.

2. The injection technique described earlier is expected to yield meaningful results that will aid in definitizing the microanatomy (vascular) of the flexor tendons. It is expected that tenorrhaphy results may be more readily determined by this technique of visualization of the microcirculation system in and around the tendinous system. Thus, work will continue to define the protocol and then apply the techniques to assist in the determination of the effects of incisions or lacerations on tenorrhaphy as related to time.

The estimated time to conclude these phases of the proposed program is illustrated on the following chart:

Study Phase	Months											
	Ju	A	S	O	N	D	Ja	F	M	A	M	Ju
A. End Attachments												
1. Distal	←						→					
2. Proximal	←											→
B. Design Refinements	←	→					←	→				
C. Basic Studies												
1. Fluid Characterization		↔		↔		↔		↔				
2. Microcirculatory				↑			↑			↑		↑
				Prtly Rept.			Mid yr. Rept.			Qrtly Rept.		Annual Rept.

6. Military Significance:

Surgery of the hand had its beginning in the Army during World War II under Surgeon General Kirk and Sterling Bunnell. Today in special military treatment centers, surgeons with specific training in Hand Surgery give expert care to the war wounded. Despite these programs aimed at restoring optimum hand function, time loss from injury and a high incidence of permanent disability remain as major problems.

Significant causes of this problem are "Stiff Hands" and muscle atrophy that result in part from edema and disuse of the upper extremity following severe injury.

If this vicious cycle of deterioration could be reversed early after injury, many able-bodied soldiers could be returned to active duty sooner and permanent disability could be significantly reduced.

We propose a common denominator to the return of early hand function — a tendon prosthesis that will link the silent muscles of the forearm to the resting skeleton of the hand early after injury.

This concept has become a realistic probability because of improved techniques in the early care of the injured hand; namely, 1) Stabilization of hand fractures by internal fixation and 2) the recent successful military programs of delayed primary closure of severe wounds in the hand and forearm.

Based on my experience over the past eight (8) years as Hand Consultant to Valley Forge General Hospital, and my background in tendon research, I believe this proposal is a forward step in the better early care of the military injury.





FIGURE 1. X-Radiographic photo of 12 week implant  
in dog metacarpal.



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# STRENGTH OF METAL TAPE IMPLANT

PATTERN NO. 1702; TYPE 304 SS

PATTERN NO. 1702B; TYPE 316 L SS

LOAD AT FAILURE, KG

LOAD AT FAILURE, KG

FIG. 2

IMPLANTATION PERIOD, WEEKS

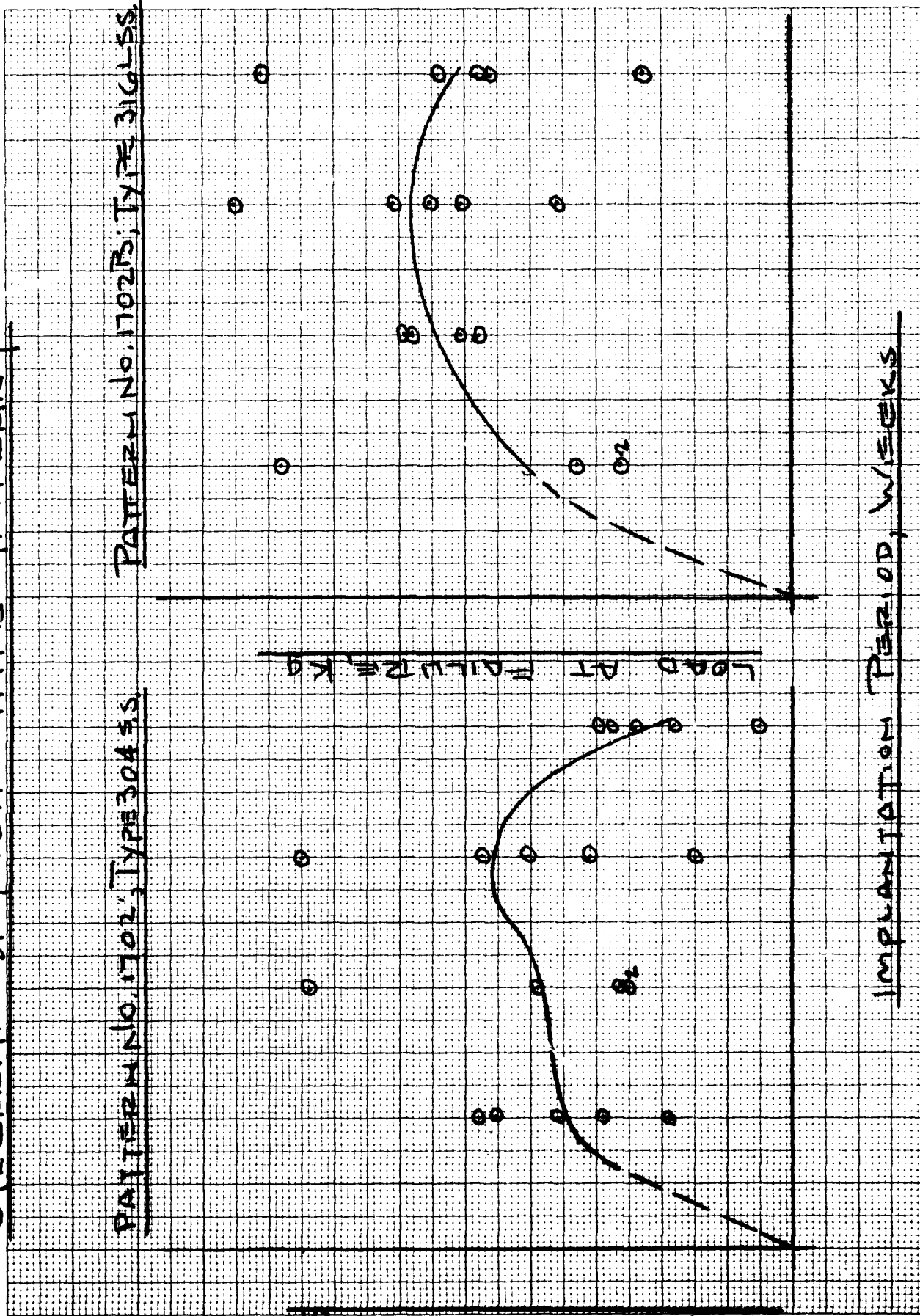




FIGURE 3. X-Radiographic photo of 12 week metacarpal implant of 1702B tape after tensile testing.





FIG. 4

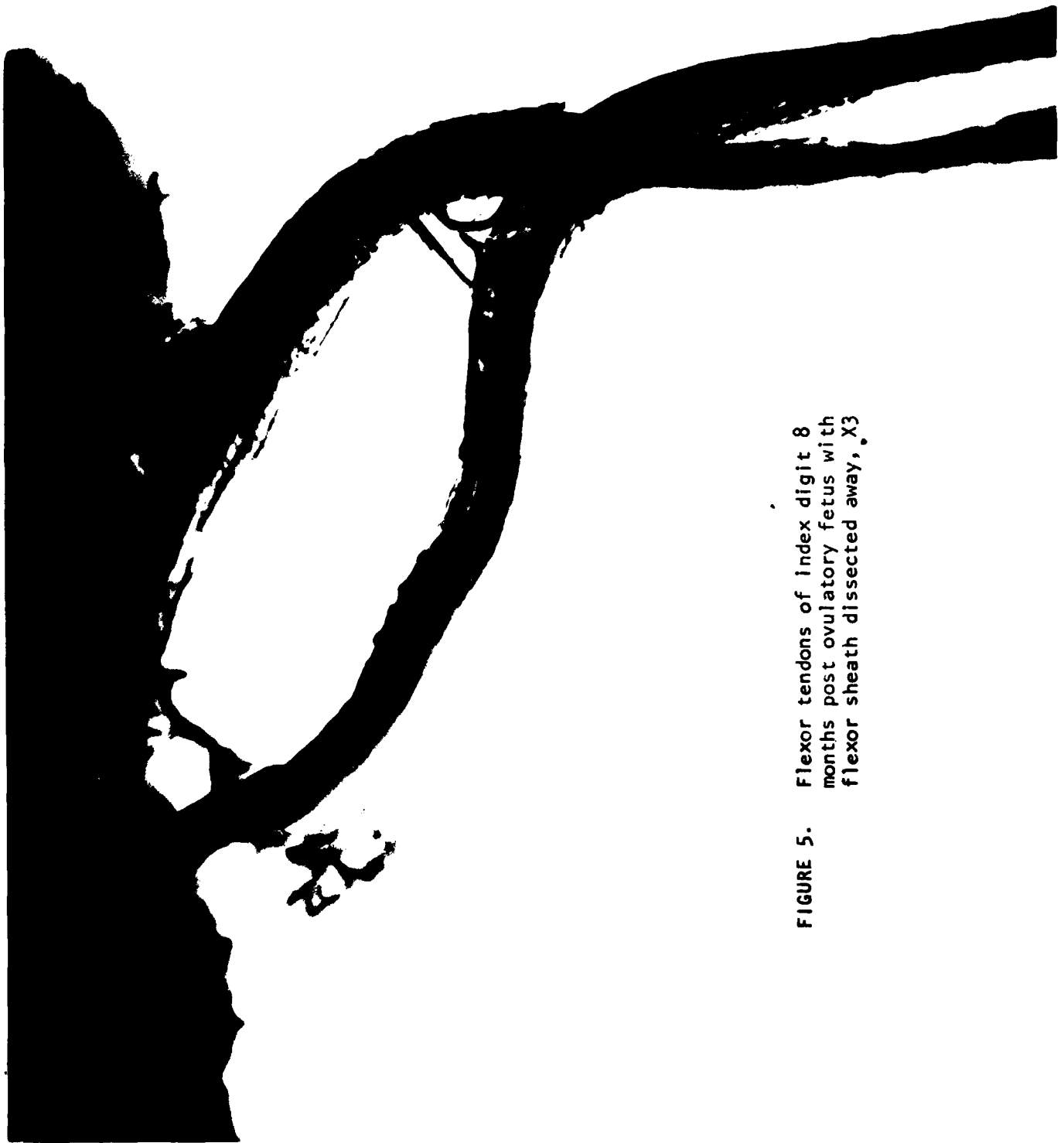
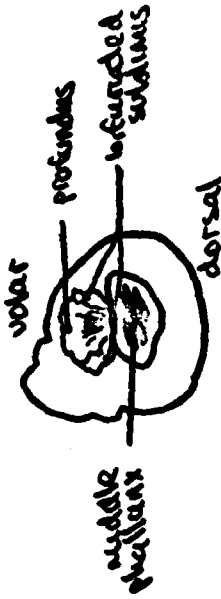


FIGURE 5. Flexor tendons of index digit 8 months post ovulatory fetus with flexor sheath dissected away, X3

FIGURE 6. Transverse section of index digit of 8 month post ovulatory fetus at level of middle phalanx showing dorsally based vascular supply. X3



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